MedSun Newsletter #58, March 2011

Safety Tips

Infant Phototherapy Light - Medical Device Safety Tips

Print Item
E–mail Item

FDA Medical Device Safety

Medical Device Safety Tips highlight what can go wrong if labeling is overlooked or not followed, and provide advice on how to mitigate risks. Commonly known as Instruction for Use manuals or package inserts, labeling includes any written material from the manufacturer accompanying medical devices. FDA's goal is to promote awareness of labeling to enhance device safety and prevent patient harm with infant phototherapy lights.

Additional Information:

FDA Medical Device Safety. Infant Phototherapy Light – Medical Device Safety Tips. February 23, 2011.
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm244306.htm[7]

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Articles

Negative Pressure Wound Therapy (NPWT) systems - Preliminary Public Health Notification (Update)

Print Item
E–mail Item

FDA MedWatch Safety Alert

FDA notified healthcare professionals of an update of activities to date involving NPWT, including a summary of additional adverse event reports received by the FDA since November 2009, additional recommendations for health care providers and patients/caregivers, as well as information learned through a special study effort.

Additional Information:

FDA MedWatch Safety Alert. Negative Pressure Wound Therapy (NPWT) systems - Preliminary Public Health Notification. February 24, 2011.

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm190704.htm[9]

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Medtronic SynchroMed II and SynchroMed EL Implantable Infusion Pump and Refill Kits: Class 1 Recall

Print Item
E–mail Item

FDA MedWatch Safety Alert

Pocket fills (the unintended injection of drugs or fluids into the patient's subcutaneous tissue at the pump pocket site instead of the pump) may result in patient harm, serious injury, and/or death due to drug overdose or underdose. Medtronic reminded healthcare professionals to check needle placement within the pump septum during the drug refill procedure. According to Medtronic, it is essential that the needle be inserted through the refill septum until it has reached the needle stop in the pump reservoir.

Additional Information:

FDA MedWatch Safety Alert. Medtronic SynchroMed II and SynchroMed EL Implantable Infusion Pump and Refill Kits: Class 1 Recall. February 16, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm243686.htm[11]

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Triad Sterile Lubricating Jelly: Recall - Product May Not Be Sterile

Print Item
E–mail Item

FDA MedWatch Safety Alert

These products may not be sterile. Immediately contact your kit, pack or tray suppliers to determine whether the products stocked at your facility are impacted by the Triad recall. Your supplier should provide you with documentation on whether your products are affected by the recall.

Additional Information:

FDA MedWatch Safety Alert. Triad Sterile Lubricating Jelly: Recall - Product May Not Be Sterile. February 16, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm243552.htm[13]

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Abbott Glucose Test Strips: Recall - False Low Blood Glucose Results

Print Item
E–mail Item

FDA MedWatch Safety Alert

FDA and Abbott Diabetes Care notified healthcare professionals and patients of a recall of 359 different lots of glucose test strips marketed under the following brand names: Precision Xceed Pro, Precision Xtra, Medisense Optium, Optium, OptiumEZ and ReliOn Ultima. Strips exposed to warm weather or prolonged storage may be more likely to provide a false result. FDA recommendations explain how to determine whether a particular lot is affected, how to order a free replacement set of strips, and what steps to take in the meantime.

Additional Information:

FDA MedWatch Safety Alert. Abbott Glucose Test Strips: Recall - False Low Blood Glucose Results. February 15, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm237910.htm[15]

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FDA orders postmarket surveillance of certain TMJ implants

Print Item
E–mail Item

FDA Press Release

Today the U.S. Food and Drug Administration ordered three manufacturers of temporomandibular joint (TMJ) implants to conduct postmarket surveillance studies to determine the length of time before the implants are removed or replaced due to pain or other reasons. The FDA is not recommending any changes on use of the implants. The agency may revise its recommendations or issue other recommendations after reviewing additional clinical data from the studies. Patients who have or are considering a TMJ implant should consult with their health care professional.

Additional Information:

FDA Press Release. FDA orders postmarket surveillance of certain TMJ implants. February 7, 2011.
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm242421.htm[17]

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FDA launches Medical Device Innovation Initiative

Print Item
E–mail Item

FDA Press Release

The FDA has proposed the Innovation Pathway, a priority review program for new, breakthrough medical devices. The new proposed Innovation Pathway program for pioneering medical devices, highlighted in a report published on the FDA's website, is part of a broader

effort underway in the FDA's Center for Devices and Radiological Health (CDRH) designed to encourage cutting-edge technologies among medical device manufacturers.

Additional Information:

FDA Press Release. FDA launches Medical Device Innovation Initiative. February 8, 2011. http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm242629.htm[19]

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Information about Metal-on-Metal Hip Implants

Print Item
E–mail Item

FDA Medical Devices: Implants and Prosthetics

In this website, the FDA describes hip implants, how metal-on-metal implants differ from other hip implants and gives information and recommendations for patients and physicians about the benefits and risks of these products.

Additional Information:

FDA Medical Devices: Implants and Prosthetics. Metal-on-Metal Hip Implants. February 10, 2011.
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/MetalonMetalHipImplants/default.htm[21]

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Arstasis One Access System: Class I Recall - Components May Fracture and/or Separate

Print Item
E–mail Item

FDA MedWatch Safety Alert

Components of the Arstasis One Access System may fracture and/or separate during use, which may result in patient harm. These products were distributed from May 14, 2010 through October 13, 2010. Customers should work with their local Arstasis territory manager to ensure product replacement.

Additional Information:

FDA MedWatch Safety Alert. Arstasis One Access System: Class I Recall - Components May Fracture and/or Separate. February 9, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm242811.htm[23]

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Merit Prelude Short Sheath Catheter Introducer: Class I Recall - Tip

Print Item

May Detach During Use

E–mail Item

FDA MedWatch Safety Alert

Introducer tip may detach during use, causing arterial injury, hemorrhaging, or other serious events, while introducer tip material may enter into the bloodstream, causing blood clots (thrombosis). Merit Medical Systems, Inc. is advising customers to immediately discontinue use of any affected product, examine their inventory, and quarantine all affected product.

Additional Information:

FDA MedWatch Safety Alert. Merit Prelude Short Sheath Catheter Introducer: Class I Recall - Tip May Detach During Use. February 4, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm242343.htm[25]

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American Regent Injectable Products: Recall - Visible Particulates in Products

Print Item
E–mail Item

FDA MedWatch Safety Alert

Recall initiated because some vials exhibit translucent visible particles consistent with glass delamination. Potential adverse events after intravenous administration include damage to blood vessels in the lung, localized swelling, and granuloma formation. Hospitals, Home Health Care Agencies, Emergency Rooms, Infusion Centers, Clinics and other healthcare facilities should not use the recalled American Regent products. Recalled products should be immediately quarantined for return.

Additional Information:

FDA MedWatch Safety Alert. American Regent Injectable Products: Recall - Visible Particulates in Products. February 5, 2011.
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm242365.htm[27]

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B. Braun Outlook 400ES Safety Infusion System, Model Number 621-400ES: Class I Recall - Hardware May Become Unresponsive

Print Item
E–mail Item

FDA MedWatch Safety Alert

Infusion systems upgraded with the Motorola compact flash hardware and supporting software, when used in a network environment that utilizes Temporal Key Integrity Protocol (TKIP) authentication, can potentially induce a memory leak that can cause the Management Processor

to become non-responsive. This causes normal operation to stop, which is signaled by an audible backup alarm indicating that the pump is not delivering the medicine. There is no visual error warning to alert the user that the pump is not working. Customers should deactivate the wireless communication on their pumps and return them to the manufacturer.

Additional Information:

FDA MedWatch Safety Alert. Braun Outlook 400ES Safety Infusion System, Model Number 621-400ES: Class I Recall - Hardware May Become Unresponsive. February 1, 2011. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm241637.htm[29]

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CDC Injection Safety

Print Item
E–mail Item

CDC

Despite safe injection recommendations, outbreaks and patient notifications resulting from healthcare personnel failing to adhere to Standard Precautions and basic infection control practices continue to be reported. This article includes CDC reminders and FAQs for healthcare personnel on critical practices for patient safety.

Additional Information:

Frequently Asked Questions (FAQs) regarding Safe Practices for Medical Injections. January 24, 2011.
http://www.cdc.gov/injectionsafety/providers/provider_faqs.html[31]

CDC. CDC Injection Safety. February 14, 2011.
http://www.cdc.gov/injectionsafety/[32]

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LabNet

Q&A with FDA's Alberto Gutierrez

Print Item
E–mail Item

AACC Clinical Laboratory News

Now at the helm of the Food and Drug Administration's (FDA) Office for In Vitro Diagnostics (OIVD) for a year and a half, Alberto Gutierrez, PhD, shared with CLN how FDA is grappling with challenges related to new technologies, shifts in clinical practice, and a move toward greater

transparency in the agency's Center for Devices and Radiological Health, under which OIVD operates.

Additional Information:

AACC Clinical Laboratory News. Q&A with FDA's Alberto Gutierrez. January 2011. http://www.aacc.org/publications/cln/2011/january/Pages/QAwithFDAsAlbertoGutierrez.aspx[34]

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Barcode Scanning Errors, a Threat to Patient Safety

Print Item
E–mail Item

AACC Clinical Laboratory News

Hospitals and other healthcare providers are relying more than ever before on barcodes for identification and tracking of patients, medications, orders, and equipment. Compared with manual data-entry error rates of one error per 300 entry events, the practice of using barcodes to rapidly link patient information to the laboratory information system is thought to be essentially error proof. Despite the improved efficiency and accuracy of barcode-based identification, a recent report demonstrates that linear barcode identification methods are not fail-safe and misidentification of patient specimens can still occur.

MedSun has received similar reports with barcode-based products. To read these events, please see the links provided in Additional Information below.

Additional Information:

AACC Clinical Laboratory News. Barcode Scanning Errors, a Threat to Patient Safety. January 2011. http://www.aacc.org/publications/cln/2011/january/Pages/Barcode%20Scanning%20Errors.aspx[36]

MedSun Report. January 7, 2009. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/medsun_details.cfm?ID=%25%22%2DG%3B%27%3FH%20%0A[37]

MedSun Report. June 23, 2009. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/medsun_details.cfm?ID=%25%22%2DK7%27%2F%3C%20%0A[38]

MedSun Report. October 22, 2008. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/medsun_details.cfm?ID=%25%22%2DC8%26OD%20%0A[39]

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Reference Intervals and Patient Safety

Print Item
E–mail Item

AACC Clinical Laboratory News

Inaccurate reference intervals can lead physicians astray and are a likely contributor to suboptimal diagnosis, suboptimal treatment, and unnecessary follow-up testing. Despite the disparities on when to establish, validate, or accept a manufacturer's reference interval, every laboratory is capable of verifying reference intervals for use in their own patient population.

Additional Information:

AACC Clinical Laboratory News. Reference Intervals and Patient Safety. January 2011. http://www.aacc.org/publications/cln/2011/january/Pages/Reference%20Intervals%20and%20Patient%20Safety.aspx[41]

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Lab QC by Risk Management

Print Item
E–mail Item

ADVANCE for Laboratory Administrators

The draft CLSI guidelines will assist labs in choosing control processes for test hazards. EP22 is intended for manufacturers and describes device hazards and possible control processes and their effectiveness to reduce risk. EP23 is intended for labs and discusses manufacturer information, local regulations and lab settings to customize QC plans. Once implemented, EP23 will guide monitoring/modification for continuous quality improvement when new hazards are identified.

Additional Information:

Lab QC by Risk Management. ADVANCE for Laboratory Administrators. May 6, 2010. http://laboratory-manager.advanceweb.com/Features/Article-1/Lab-QC-by-Risk-Management.aspx[43]

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HeartNet

Non-evidence-based ICD implantations in the United States

Print Item
E–mail Item

PubMed Abstract

Practice guidelines do not recommend use of an implantable cardioverter-defibrillator (ICD) for

primary prevention in patients recovering from a myocardial infarction or coronary artery bypass graft surgery and those with severe heart failure symptoms or a recent diagnosis of heart failure. Among patients with ICD implants in this registry, 22.5% did not meet evidence-based criteria for implantation.

Additional Information:

Non-evidence-based ICD implantations in the United States. PubMed Abstract. January 2011. http://www.ncbi.nlm.nih.gov/pubmed/21205965[45]

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HomeNet

MedSun In Action - Negative Pressure Wound Therapy (NPWT): Special Study Summary

Print Item
E–mail Item

Please see this month's MedSun in Action section for a summary describing what FDA learned about device issues faced by caregivers who use NPWT in the home setting or in other non-hospital environments.

Additional Information:

March 2011 MedSun Newsletter. MedSun in Action. Negative Pressure Wound Therapy Special Study Summary. Online Available: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=58#22[47]

FDA MedWatch Safety Alert. Negative Pressure Wound Therapy (NPWT) systems - Preliminary Public Health Notification. February 24, 2011. http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm190704.htm[48]

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KidNet

Information about Luer Misconnections

Print Item
E–mail Item

FDA Websites

Patient injuries and deaths have occurred when different device delivery systems are mistakenly

connected to each other. These errors are often facilitated by fittings called Luer connectors, which can allow different systems to be easily, but erroneously, connected. FDA has taken various actions to help educate healthcare professionals about these dangerous misconnections.

Additional Information:

FDA Medical Device Safety. Luer Misconnections. May 12, 2009.
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm134863.htm[50]

FDA MedSun. Luer Connector Misconnections: Under-Recognized but Potentially Dangerous Events – Complete Webcast Transcript
http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/ucm127745.htm[51]

FDA Patient Safety News (video). More Patient Deaths from Luer Misconnections. October 2007.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=68#5[52]

FDA Medical Device Safety. Reduce and Report – Enteral Feeding Tube Misconnections. November 2010.
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm234440.htm[53]

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Medical Device Safety Tip about Infant Phototherapy Light

Print Item
E–mail Item

FDA Medical Device Safety Tip

Please see this month's safety tip about preventing patient injuries with infant phototherapy lights.

Additional Information:

March 2011 MedSun Newsletter reference. Online Available:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/news/newsletter.cfm?news=58#1[55]

FDA Medical Device Safety. Infant Phototherapy Light – Medical Device Safety Tips. February 23, 2011.
http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm244306.htm[56]

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Discussions with Healthcare Providers

Negative Pressure Wound Therapy (NPWT): Special Study Summary

Special Study Summary
Survey Topic: Negative Pressure Wound Therapy (NPWT)
Year Conducted: 2009-2010
Reference OMB No. 0910-0500

Background
The effort was to learn about device issues faced by professional home care providers, as well as those issues potentially encountered by lay caregivers who use NPWT in the home setting or in other non-hospital environments. While the FDA has received reports of problems with the use of NPWT, feedback from providers can help to promote a better understanding of why these adverse events occur and also inform FDA if other types of events have occurred.

Participants were recruited from the Medical Product Safety Network (MedSun) facilities and from professional organizations that represent home care providers or advocate on behalf of wound care patients. Instruments included: a Web survey questionnaire; a semi-structured questionnaire for telephone interviews; and a self-administration questionnaire (SAQ). Three-hundred and forty two respondents completed the Web survey questionnaire, which ran for two months. Fifteen one-hour telephone interviews were conducted with seventeen participants using the semi-structured questionnaire; five participants completed the SAQ. Questions were based on the following topics: Device Performance and Experience, Prescription and Discharge Planning, Training and Labeling, Issues Associated with Dressings, Patient Outcome.

Summary
The most common NPWT systems used by respondents include the KCI Wound V.A.C.[1] product line, mainly the ActiV.A.C. and V.A.C. Freedom[2]. Other commonly used systems were the Smith and Nephew (formerly Blue Sky) models.

A model mentioned often by the phone/SAQ respondents was the ConvaTec Engenex. Phone /SAQ respondents were more likely to indicate complications, notably bleeding, infection, pain, retained foam and tissue adherence, whereas Web respondents primarily cited infection and bleeding issues.

According to phone/SAQ respondents, prescription (patient selection, wound type, length of use), discharge planning and training tend to vary as a function of the facility type (hospital, outpatient clinic, Home Health Agency [HHA])[3]. These respondents felt that issues arise when there is a poor transition from the hospital to home and when the devices are not initially ordered, prescribed, set up or applied by a certified wound specialist or an experienced professional. Other problems were attributed to the prescriber's lack of specific education about wound management therapy.

Respondents indicated that lay caregivers and patients are largely trained on the meaning of alarms, how to troubleshoot, how to change drainage canisters, how to identify an emergency and what to do in an emergency situation. Respondents were generally happy with the lay-caregiver/patient educational materials, training and support provided by the manufacturer. Although most Web respondents thought all or some of these device labels and instructions were written for a lay audience, nearly two-thirds indicated they observed challenges with caregivers' and patients' ability to follow device instructions. Of those who observed challenges, the majority attributed them to patients' or caregivers' distractibility, whether because of their illness, altered consciousness, or other medical situation. A few phone/SAQ respondents suggested condensing the materials for the patient or to write them at a 5th or 6th grade reading level. Some had even written their own instructions to make them more understandable to the patient.

Respondents stated patients or lay caregivers should not be administering the therapy because they aren't trained to understand the complexities and intricacies of wound care, and also because clinical professionals are needed to monitor and assess the wound in addition to changing the dressing.

Dressings were changed often, 2-3x per week, as indicated in the instructions. However, phone respondents stated that problems can arise when the dressing is changed too often, or not frequently enough.

Overall, respondents felt that there is a definite benefit to NPWT therapy, regardless of the care setting and that it is a safe therapy when prescribed and administered appropriately. Safety and effectiveness in neonatal and pediatric patients has not been determined at this time, necessitating future study – a recommendation provided by phone respondents. Users generally are happy with the systems they use and the company support they and their patients receive.

Respondents said there should be more prescriber education about when therapy can and should be used and, equally important, when it should be stopped. Some expressed the opinion that NPWT is overprescribed mainly because of aggressive marketing tactics. Phone/SAQ respondents, especially directors of wound care centers, said that home care providers need to be more experienced when it comes to administering wound care and changing dressings. Opportunities to gain more experience and expertise should be afforded to those who provide care. They also felt there needs to be more consistent patient and wound monitoring, especially in the home setting.

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Special Studies and Surveys are two of many tools the Agency is using to evaluate the public health impact of the potential problems associated with the use of medical devices. Additionally, FDA continues to receive adverse event reports from its Medical Device Reporting program. FDA will also continue to make use of the literature and other published information. FDA scientific, medical, nursing and engineering staff are made aware of the survey results as needed. If FDA believes there is a significant risk of adverse events as noted from the survey, it will combine those results with data gained from the other sources. FDA will work with the manufacturers and health care professional organizations to make important information known
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to the clinical community. Additionally, FDA continues to work with manufacturers to ensure the development, testing and promulgation of methods for reducing the risk associated with these devices and to minimize the complications from adverse events that may occur in the course of normal usage. If the results of any survey raise serious concerns about the safety of these devices, FDA may convene an Ad Hoc group of clinical and manufacturing representatives to discuss further actions.
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[1] *Vacuum Assisted Closure (V.A.C.)*

[2] *Note: of all the respondents surveyed, KCI was the most common system used and is why majority of the findings refer to this particular manufacturer's product line.*

[3] *Web respondents were not asked about discharge planning because respondents are primarily home care providers, who provide patient care regardless of how the therapy migrates into the home.*

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Highlighted MedSun Reports

Highlighted Reports

Print Item
E–mail Item

This section contains a sample of reports from all the MedSun reports received during a particular period. The reports were submitted by MedSun Representatives. In some instances the reports have been summarized and/or edited for clarity. The entries that follow represent a cross section of device-related events submitted by MedSun reporters during the period December 1 through December 31 2010. All other reports can be searched under the 'MedSun reports' menu pane. Note: the two month delay is due to quality control and follow-up.

ANESTHESIOLOGY

Device 1:
Type: Fiber Optic Blade
Manufacturer: Flexicare Medical Limited
Brand: Briteblade Pro
Model#: Macintosh Size 3
Lot #: 0120

Device 2:
Type: Laryngoscope Handle
Manufacturer: Flexicare Medical Limited
~~~~~~~~~~

Brand: Venticaire
Lot #: CHT

Problem:
During an attempt to place an intubation tube during a code, the user retrieved a laryngoscope handle and MAC #3 laryngoscope blade to assemble for ET tube placement. When the two sections were snapped together and mated, no light was emitted. Several attempts were made to get the lamp to start, including battery position and re-insertion. The code team had to scramble for another adult intubation tray to get another laryngoscope set. The second set worked and the code team was able to position the ET tube. At the end of code, the respiratory therapist tested the known bad MAC3 blade with another handle and the blade lit. The therapist also tested a different blade onto the known failed handle and the blade lit; we cannot get either the blade or handle to fail when matched with different mates. Sterile processing has been instructed to test the light on the handle by pressing the light housing down unit lit. The blades are usually packaged sterile and are unable to be tested with each handle. These were purchased by the medical center to avoid this very scenario. Distributer of device contacted for manufacturer information. This is a reoccurring issue according to the therapists.
==========
Health Professional's Impression
==========
Device failed to work during a code event and a STAT replacement process had to occur. It has been reported that more than one event has occurred with this new disposable system.
==========
Manufacturer response for Laryngoscope, Bright Blade Pro
==========
To hand off instrument to distributor.
==========
Manufacturer response for Laryngoscope Handle, Venticaire
==========
Return to distributor for evaluation. This is to be returned as a SET along with the blade.

Device:
Type: Prone Position Head Cushion
Manufacturer: Vital Signs, Inc.
Brand: Disposa-view
Lot #: 201005
Cat #: 8000HDP

Problem:
Patient was in a prone position for a surgical procedure for more than 4 hours that resulted in a reddened area across the forehead when the patient was returned to the supine position. A few months later patient has presented with a 3 cm non-healing lesion to his forehead that is requiring additional intervention by Plastics/Dermatology.

No other problems noted with this product in the past.

==========
Health Professional's Impression
==========
Decreased circulation to the area (forehead)for a period of time.
==========
Manufacturer response for Prone Position Pillow, Disposa-View Disposable Prone Position Head Cushion
==========
There has been no change in the product (i.e. density of the foam or change in product design).

Device:
Type: Regulator
Manufacturer: Controls Corporation of America
Brand: Carbon Dioxide Regulator
Model#: 3042001-01-0XB

Problem:
We were using a CO2 tank prior to procedure. We connected the valve and proceeded to push the button on the side to let the CO2 flow out of the tank. The button pushed down quite hard and then there was a big "bang" sound, much like a gun going off. Turns out the pressure must have built up and the regulator wasn't working. The valve exploded and broke. Couldn't hear well immediately afterwards. Now there is pain in both ears. Mostly in the right ear, and it is much like the start of an ear infection.

CARDIOVASCULAR

Device:
Type: Aortic Bioprothesis Valve
Manufacturer: Edwards Lifesciences
Brand: Carpentier-edwards Perimount Magna Ease Pericardial Bioprothesis-aortic
Model#: 3300TFX

Problem:
Aortic valve placed on the sterile field. As scrub nurse was rinsing the valve, she noticed unusual markings on the inner leaflets of the valve. Surgeon notified. Valve removed from the field and will be returned to the tissue supplier.

Device:
Type: Arrowgard Blue Triple Lumen Central Line Catheter
Manufacturer: Arrow International
Brand: Arrow Bluegard
Lot #/ Cat #: RF8123993

Problem:
Patient washed with chlorhexidine wash evening before and experienced itching with a rash. Self-treated with Benadryl and presented to preop the following morning. Reaction to the wash was explained to the nurse and an "allergy" was recorded. The usual oral rinse with chlorhexidine gluconate 0.12% was completed. Forty-five minutes later a central line was inserted in preparation for the Coronary artery bypass graft (CABG) procedure. Shortly thereafter the patient experienced shortness of breath, and demonstrated "seizure-like" movement. He was intubated to protect his airway and surgery was cancelled. In addition to the central line and oral rinse, staff utilized chlorhexidine hand gel throughout their contact with the patient while prepping him for surgery.

Device:
Type: Arterial Line
Manufacturer: Arrow International
Brand: Arrow Arterial Line Cath Kit
Model#: UM-04018
Lot #: RF0090664
Other #: 18GA. 16cm. 025in. dia.

Problem:
The physician assistant was attempting to place an right femoral arterial line. The spring wire guide was unable to retract or advance once inside the needle. Device was removed and another femoral arterial line set had to be used.

Device:
Type: Catheter, Introducer
Manufacturer: Abbott Vascular
Brand: Viking Guiding Catheter
Model#: 1001966-07
Lot #: 0060791
Other #: 7fr Mpa 2 guiding catheter

Problem:
Catheter tip was misshapen prior to removal from packing. A second catheter had the same issue. The tip seemed to be misshapen. It seemed to be a packaging issue because the tip seemed to get squished against the package holder.

Device:
Type: Clamp, Vascular
Manufacturer: St. Jude
Brand: Femostop Gold
Model#: 11165

Problem:
An elderly patient with femostop compression device applied to thigh. Red tab removed from device. Nurse noted that the number on the monitor registered 100mm/hg. Nurse pumped the device to achieve pressure for hemostasis/groin management of hematoma. The patient then experienced a drop in BP. RN released pressure on FemoStop from 125 to 86. Patient was fluid resuscitated and blood pressure increased. When the nurse attempted to remove the device she opened the white clip on the device and turned the knob on the bulb completely to the left to deflate. The dome of the device would not deflate. The device was removed from the patient and the nurse attempted to remove the air from the dome. Dome would still not deflate. New device applied. The RN placed the device in an office and two days later pressure still read 18 mm/hg.
==========
Health Professional's Impression
==========
The device would not deflate.
==========
Manufacturer response for Femostop Gold, FemoStop Gold
==========
Manufacturer sent representative from Sweden to review

Device:
Type: Coronary Drug-eluting Stent
Manufacturer: Boston Scientific
Brand: Promus
Lot #: 0061141

Problem:
Stent found to be bent onto the packaging stylette. This was not observed initially by the physician nor the scrub tech. It was later found that the stent was not on the delivery device at the time of insertion. The balloon was inflated over the lesion. It was then discovered that the stent was still located under the yellow wrapping tool on the stylette.
==========
Health Professional's Impression
==========
No adverse event. The stent was apparently damaged during the manufacturing process.

Device:
Type: Introducer Catheter
Manufacturer: Arrow International, Inc
Brand: Arrow Select Kits
Model#: UW-09801-SP
Lot #: RF 0091803

Problem:
The introducer catheter leaked while in place in the patient. This has happened with several of

these catheters where either blood or IV fluids leaked out of the top of the introducer and have had air in the side port. It appears that the valve in the introducer catheter does not work properly. No patient has been harmed.
==========
Health Professional's Impression
==========
possible faulty valve in introducer catheter
==========
Manufacturer response for Central line introducer catheter, Arrow Select Kits
==========
Manufacturer has requested that device be returned for analysis

EAR, NOSE & THROAT

Device:
Type: Tube, Tympanic
Manufacturer: Gyrus ACMI, Inc.
Brand: Micron Titanium Bobbin Ventilation Tube
Model#: 14-5272
Lot #: 0625683013
Cat #: 14-5272

Problem:
Patient had previous ossicular reconstructive surgery. After about two months, patient unable to hear. Physician brought patient to OR to do another ossicular reconstruction and noted during surgery the prosthesis from the initial surgery was broken. Prosthesis removed and a new one implanted.
==========
Health Professional's Impression
==========
Unknown

GENERAL & PLASTIC SURGERY

Device:
Type: Applier, Clip
Manufacturer: Ethicon Endo Surgery
Brand: Ligamax 5
Model#: EL5ML
Cat #: EL5ML
Lot #: G4TU6E

Problem:
Surgeon was performing a laparoscopic cholecystectomy with intraoperative cholangiogram.

When surgeon applied the first clip to the patient's artery, the Ligamax 5 mm Endoscopic Multiple Clip Applier would not release after firing. The clip applier was jammed and the device would not revert back to the open position. The concern was that the artery could have been damaged. The only other option would have been to open the abdomen and try to free the device. However, the surgeon was able to safely remove the clip off the artery with the clip applier still in the closed position. No injury was done to the patient, but this put the patient at risk and the surgeon had to make a decision to try to work the device off or open the patient up to try to remove it. This posed a significant issue during the procedure. Another clipper was used from the same lot number without a problem.
==========
Health Professional's Impression
==========
Device would not release after clipping artery.

Device:
Type: Endo Clip
Manufacturer: Covidien/US Surgical
Brand: Autosuture Endo Clip
Model#: REF 176630
Lot #: N0H0411

Problem:
Child admitted with lesion in his left lower chest. Child underwent a video assisted thorascopic surgery. During the procedure, after two clips had been placed on an artery, the clip applier jammed during the placement of the third clip. The surgeon replaced clip applier with another to place the third clip and then performed a partial transection of the artery. The first two clips; however had not closed the artery and the bleeding necessitated conversion of the thorascopic procedure to an open chest procedure.

Device:
Type: Instrument, Surgical
Manufacturer: Spineology Inc
Brand: Spineology EShaper Blade
Model#: 315-0014

Problem:
During a lumbar laminectomy and fusion L4-5, L5-S1 the tip of the Spineology Shaver blade broke off in the L5 disc space.

Device:
Type: Suction Coagulator

Manufacturer: A & E Medical
Brand: Suction Coagulator
Pack lot # 987873
Cat #: 139926
Other #: A & E Medical packaged inside a PHS [Professional Hospital Supply] special made Tonsil/Adenoid Pack.

Problem:
On the wand of the device there is unknown dark gold colored dust.

GENERAL HOSPITAL

Device:
Type: Catheter, Picc
Manufacturer: Medical Components, Inc
Brand: Vascu-picc
Lot #: MBBK 950
Other #: Ref # MRVSP41003

Problem:
Leaking noted at the PICC catheter site. Small tear noted above hub on the clear part of the tubing. PICC removed.

Device 1:
Type: Infusion Pump, Patient Controlled Analgesic
Manufacturer: Smiths Medical ASD Inc.
Brand: Cadd Solis
Model#: Cadd solis 2100

Device 2:
Type: Infusion Pump, Patient Controlled Analgesic
Manufacturer: Smiths Medical ASD Inc.
Brand: Cadd Solis
Model#: Cadd solis 2100

Problem:
We have had multiple reports of the PCA button not working appropriately with our new CADD Solis pumps. In all the reported incidents nurses indicated that the patient was pushing the PCA button in an attempt to receive pain medication but the pump was not registering the button presses. Pump registered that the attempts were 0. Switching out to a different cord solved the problem in one case; in others the nurse simply replaced the pump. Clinical engineering was able to validate that there was a problem with the cords, but they were not able to pinpoint the point of failure.

These pumps and associated cords are only 4 months old. We have seen failures in 4 of our 28 pumps.
==========
Health Professional's Impression
==========
The failure of the PCA pump cords caused a delay of medication, and inadequate pain control.

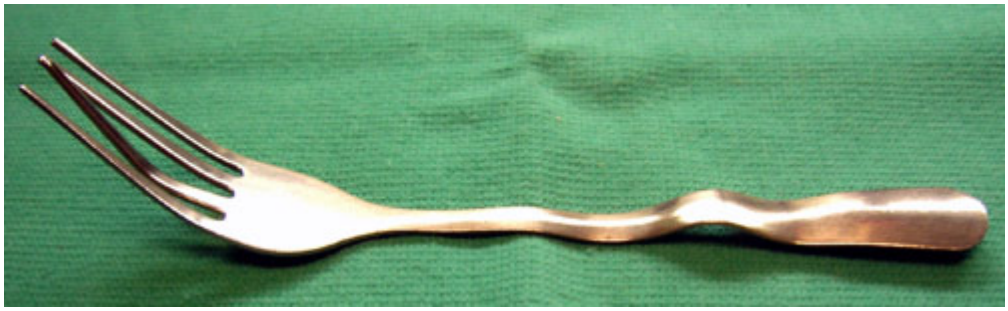
Device:
Type: Pump, Infusion, Elastomeric
Manufacturer: I-FLOW CORPORATION
Brand: On-q
Model#: CB6004
Lot #: 082294

Problem:
The pain service RN called the patient at home to follow up pain control with an I-Flow ON-Q pain pump. Patient stated it leaked so badly that after he'd gone through 7 shirts, he stopped using the pump. Patient returned pump to hospital, and we will return to I-Flow Corporation to investigate. This was a 600mL pump, Lot #082294, Model #CB6004. It was filled to 700mL, which the manufacturer says is okay.

Device:
Type: Pump, Infusion, Pca
Manufacturer: CareFusion 303, INC.
Brand: Alaris Pca Module
Model#: 8120

Problem:
A patient bent a metal fork into a specific shape that allowed him to disengage the plunger mechanism on an Alaris 8120 PCA Module. Once the plunger head was raised above the syringe the patient pressed down on the syringe plunger and self-administered 13mg of Dilaudid. Patient was found unconscious and in respiratory arrest with an O2 sat level of 40%. A reversing agent was administered. After the patient recovered he admitted what he had done, produced the fork and demonstrated how he was able to manipulate the PCA Module. A Clinical Engineering technician was able to duplicate the event. The PCA Module and the fork have been sequestered for further investigation.
==========
Health Professional's Impression
==========
The design of the syringe cover allows the introduction of very thin objects into the compartment containing the PCA syringe. There is a very small crack between the two cover halves (1 to 2 mm) when the cover is locked. A tool can be used to turn the release knob and disengage the plunger head if the tool is bent in a very specific pattern.

See device images:



Device:
Type: Warmer, Infant Radiant
Manufacturer: Draeger
Brand: Babytherm 8004

Problem:
Nursing reported the following.

Temperature probe connected to patient and bed and temp settings set to 36.5. Open warmer showed patient's temp at 37.3, but still within normal limits. Heart rate was high so temperature was checked rectally which showed a temp of 39.0. Patient's temperature should have been

regulated correctly with open warmer being connected to patient through temperature probe. The infant was removed and placed in another warmer; monitored vital signs closely.

It was determined that this overheating was caused by a known problem referred to as the Stem Effect. (Technical information available here http://bit.ly/eb6nZI)

Our current policy is to coil the temperature probe to avoid the effects of the Stem effect. Our policy is as follows:

Thermoregulation for all patients admitted into radiant warmers and incubators:
1. Warm bed prior to admission. See CPG table Neutral thermal environment for temperature range to select. (This requires weight and age of patient)

2. Select proper skin temp probe.

3. For low-birthweight patients and those with fragile skin, place a barrier of duoderm between the temp probe cover and patient skin.
a) Cut the duoderm into a circle. Cut out the center portion. Place this against the skin.
b) Place the temp probe into the center of the duoderm against the skin.
c) Make a few coils of the temp probe wiring under the temp probe cover, and place this cover over the duoderm.

4. For patients without specialized skin care needs, place the temperature probe and coils of wiring on the sticky surface of the temperature probe cover and place this on the patient's body.

5. Ensure the incubator/ radiant warmer is set to skin control or servo control, rather than air temperature or manual.

6. Adjust control temperature to maintain baby within normal range. Measure axillary temperatures with cares.

Coiling prevents inadvertent cooling of the temperature probe tip, and helps to maintain a consistent temperature. Improper technique in placing skin probe can cause inadvertent over heating of the patient. We originally found out about the stem effect in 1993. Manufacturer was involved at that time.

PHYSICAL MEDICINE

Device:
Type: Heel Warmer, Infant
Manufacturer: DeRoyal
Cat #: HNICU-100

Problem:
Heel warmer was activated by phlebotomist. The device is hard to activate and requires a significant amount of pressure to do so.

The warmer ruptured, splashing the phlebotomist in the face and forearm. She experienced a burning sensation. She immediately flushed the affected areas with water and then went to the Emergency Room for care. The employee was noted to have erythema to her left cheek and minimal erythema to her forearm. She was sent home by the Emergency Department (ED) physician to shower with unscented soap and instructed to treat the areas with Aloe Vera or antibiotic ointment.

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 *Special Note: The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as less than 21 years of age.*

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Medical Device Problem Summaries

Summary of MedSun Reports Describing Problem With Arthroscopic Shaver Blades and Burrs

Print Item
E–mail Item

Arthroscopic shaver blades and burrs are devices used for the resection of bone and tissue within the interior of a joint. These products are considered to be accessories to an arthroscope, which is defined as an, "electrically powered endoscope intended to make visible the interior of a joint." (21 C.F.R. pt 888.1100)

Many arthroscopic blades and burrs are initially marketed as single-use devices (SUD). The term "single-use device" refers to a device that is intended for one use, or on a single patient during a single procedure. A reprocessed SUD is an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. SUDs may be re-processed by another manufacturer if the device re-processor has received clearance from the Food and Drug Administration (FDA, 2009). The reports described in this summary include both SUDs and reprocessed SUDs.

Over the past 2 years, MedSun has received 44 adverse event reports associated with Arthroscopic Shaver devices manufactured by Ascent Healthcare Solutions, ConMed Linvatec, Smith & Nephew, and Stryker Endoscopy. The reports were submitted by 22 hospitals between February 2009 and February 2011.
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The reported device problems were:
• 22 – Expulsion of metal debris during use
• 9 – Mechanical failure (e.g. blade breakage) during use
• 5 – Failure of the blade/burr to rotate
• 4 – Dullness of the blade/burr
• 3 – Compromised device sterility
• 1 – Out-of-the-box mechanical defect (e.g. blade/burr found to be bent)

None of the reported events involved a patient death or injury. Of the reports that listed patient age, 5 had a patient age listed as less than 21 years and 33 had a patient age listed as greater than 21 years. Of the reports that listed patient gender, a total of 16 reports involved female patients and a total of 23 reports involved male patients.

These MedSun reports summarized above, in addition to manufacturer, healthcare, and voluntary reports contributed to FDA awareness of the device problems.

The following recall(s) are associated with arthroscopic shaver blades and systems since 2009. The Medsun Reported events may, or may not, be involved in the recall(s) listed.

Recall Number: Z-0825-2011
Date Posted: December 28, 2010
Product: Stryker brand End Cutter Shaver Blade F-Series, 4.0 mm; Model Number -375-747-000
Code Information: Lot Number: 09203CE2
Recalling Firm/Manufacturer: Stryker Endoscopy
Action: Stryker issued Urgent Product Recall letters dated November 12, 2009 to all its direct consignees, informing them of the affected products and providing instructions on the recall. Customers were requested to return the product to Stryker. Stryker can be contacted concerning this recall at 408 754-2124.
Distribution: Nationwide Distribution: includes: Arizona, California, Colorado, Denver, Florida, Hawaii, Illinois, Kansas, Kentucky, Massachusetts, Michigan, New York, Ohio, and South Carolina.

Information online: http://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfRES/res.cfm?id=88337

Recall Number: Z-1565-2009
Date Posted: July 14, 2009
Product: Smith & Nephew Endoscopic Disposable Blades: BOXED F/R,BL,4.5MM,SERIES 3000 /6 Product #: 7206011. DYONICS Series 3000 BONECUTTER
Code Information: Lot #: 20148714 and 20153849.
Recalling Firm/Manufacturer: Smith & Nephew, Inc. Endoscopy Division
Action: Smith & Nephew, Inc. issued a notification letter dated May 5, 2009 via Federal Express to User Facility and/or Sales Representatives on May 7, 2009 and an Email was sent to Sales Representatives. Accounts were requested to 1)complete the form and fax to Smith & Nephew,

Inc. at 1-508-261-3636 and 2) return (using the firm's return authorization number) affected product to Smith & Nephew, Inc. Direct questions about this recall to Smith & Nephew, Inc. by calling 1-508-261-3655.
Distribution: Worldwide Distribution: -- US, Switzerland, Canada, United Arab Emerites, Belgium, Mexico, South Africa, Great Britain, Australia, Korea, Japan, Germany, Israel, India, Taiwan, Greece, Italy, Turkey and Chile

Information online: http://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfRES/res.cfm?id=81979

Recall Number: Z-1564-2009
Date Posted: July 14, 2009
Product: Smith & Nephew Endoscopic Disposable Blades: DISPOSABLE BL,4.5MM FR ELITE Part #: 7210499. DYONICS Series 3000 BONECUTTER
Code Information: Lot #: 20153865.
Recalling Firm/Manufacturer: Smith & Nephew, Inc. Endoscopy Division
Action: Smith & Nephew, Inc. issued a notification letter dated May 5, 2009 via Federal Express to User Facility and/or Sales Representatives on May 7, 2009 and an Email was sent to Sales Representatives. Accounts were requested to 1)complete the form and fax to Smith & Nephew, Inc. at 1-508-261-3636 and 2) return (using the firm's return authorization number) affected product to Smith & Nephew, Inc. Direct questions about this recall to Smith & Nephew, Inc. by calling 1-508-261-3655.
Distribution: Worldwide Distribution: -- US, Switzerland, Canada, United Arab Emerites, Belgium, Mexico, South Africa, Great Britain, Australia, Korea, Japan, Germany, Israel, India, Taiwan, Greece, Italy, Turkey and Chile.

Information online: http://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfRES/res.cfm?id=81978

Recall Number: Z-1560-2009
Date Posted: July 14, 2009
Product: Smith & Nephew Endoscopic Disposable Blades: FULL RADIUS BLADE, 5.5MM,SER
3000 Part #: 7206010. DYONICS Series 3000 BONECUTTER
Code Information: Lot #: 20154971 and 20148707.
Recalling Firm/Manufacturer: Smith & Nephew, Inc. Endoscopy Division
Action: Smith & Nephew, Inc. issued a notification letter dated May 5, 2009 via Federal Express to User Facility and/or Sales Representatives on May 7, 2009 and an Email was sent to Sales Representatives. Accounts were requested to 1)complete the form and fax to Smith & Nephew, Inc. at 1-508-261-3636 and 2) return (using the firm's return authorization number) affected product to Smith & Nephew, Inc. Direct questions about this recall to Smith & Nephew, Inc. by calling 1-508-261-3655
Distribution: Worldwide Distribution: -- US, Switzerland, Canada, United Arab Emerites, Belgium, Mexico, South Africa, Great Britain, Australia, Korea, Japan, Germany, Israel, India, Taiwan, Greece, Italy, Turkey and Chile

Information online: http://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfRES/res.cfm?id=81974

Recall Number: Z-1561-2009
Date Posted: July 14, 2009
Product: Smith & Nephew Endoscopic Disposable Blades: STONECUTTER ACR,4.0,EP-1,DSP
Part #: 7205330. DYONICS Series 3000 BONECUTTER
Code Information: Lot #: 20153856.
Recalling Firm/Manufacturer: Smith & Nephew, Inc. Endoscopy Division
Action:
Distribution: Worldwide Distribution: -- US, Switzerland, Canada, United Arab Emerites, Belgium, Mexico, South Africa, Great Britain, Australia, Korea, Japan, Germany, Israel, India, Taiwan, Greece, Italy, Turkey and Chile.

Information online: http://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfRES/res.cfm?id=81975

Recall Number: Z-1566-2009
Date Posted: July 14, 2009
Product: Smith & Nephew Endoscopic Disposable Blades: INCISOR BLADE,3.5MM DSPL,EP-1
Part #: 7205312. DYONICS Series 3000 BONECUTTER
Code Information: Lot #: 20153858.
Recalling Firm/Manufacturer: Smith & Nephew, Inc. Endoscopy Division
Action: Smith & Nephew, Inc. issued a notification letter dated May 5, 2009 via Federal Express to User Facility and/or Sales Representatives on May 7, 2009 and an Email was sent to Sales Representatives. Accounts were requested to 1)complete the form and fax to Smith & Nephew, Inc. at 1-508-261-3636 and 2) return (using the firm's return authorization number) affected product to Smith & Nephew, Inc. Direct questions about this recall to Smith & Nephew, Inc. by calling 1-508-261-3655.
Distribution: Worldwide Distribution: -- US, Switzerland, Canada, United Arab Emerites, Belgium, Mexico, South Africa, Great Britain, Australia, Korea, Japan, Germany, Israel, India, Taiwan, Greece, Italy, Turkey and Chile.

Information online: http://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfRES/res.cfm?id=81980

Recall Number: Z-1562-2009
Date Posted: July 14, 2009
Product: Smith & Nephew Endoscopic Disposable Blades: NOTCHBLASTER ABR,EP-1,5.5 DSPL
Part #: 7205329. DYONICS Series 3000 BONECUTTER
Code Information: Lot #: 20153855
Recalling Firm/Manufacturer: Smith & Nephew, Inc. Endoscopy Division
Action: Smith & Nephew, Inc. issued a notification letter dated May 5, 2009 via Federal Express to User Facility and/or Sales Representatives on May 7, 2009 and an Email was sent to Sales Representatives. Accounts were requested to 1)complete the form and fax to Smith & Nephew, Inc. at 1-508-261-3636 and 2) return (using the firm's return authorization number) affected product to Smith & Nephew, Inc. Direct questions about this recall to Smith & Nephew, Inc. by calling 1-508-261-3655.

Distribution: Worldwide Distribution: -- US, Switzerland, Canada, United Arab Emerites, Belgium, Mexico, South Africa, Great Britain, Australia, Korea, Japan, Germany, Israel, India, Taiwan, Greece, Italy, Turkey and Chile.

Information online: http://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfRES/res.cfm?id=81976

Recall Number: Z-1567-2009
Date Posted: July 14, 2009
Product: Smith & Nephew Endoscopic Disposable Blades:TURBOWHISKER BLD,EP-1,4.5MM(6)
Part #: 7205316. DYONICS Series 3000 BONECUTTER
Code Information: Lot # : 20153874.
Recalling Firm/Manufacturer: Smith & Nephew, Inc. Endoscopy Division
Action: Smith & Nephew, Inc. issued a notification letter dated May 5, 2009 via Federal Express to User Facility and/or Sales Representatives on May 7, 2009 and an Email was sent to Sales Representatives. Accounts were requested to 1)complete the form and fax to Smith & Nephew, Inc. at 1-508-261-3636 and 2) return (using the firm's return authorization number) affected product to Smith & Nephew, Inc. Direct questions about this recall to Smith & Nephew, Inc. by calling 1-508-261-3655
Distribution: Worldwide Distribution: -- US, Switzerland, Canada, United Arab Emerites, Belgium, Mexico, South Africa, Great Britain, Australia, Korea, Japan, Germany, Israel, India, Taiwan, Greece, Italy, Turkey and Chile.

Information online: http://www.accessdata.fda.gov/scrIpts/cdrh/cfdocs/cfRES/res.cfm?id=81982

The following table lists the MedSun reports that are described in the device problem summary above.
[Note: The reports have been edited for clarity]

Reports of Problems with Arthroscopic Shaver Blades and Burrs

Device	Catalog Number, Model Number, Lot Number	Event Description
Smith & Nephew, Inc.,, Dyonics Synovator	7205334, N/A, 50530083	Male patient was undergoing right shoulder arthroscopy, arthroscopic biceps tenodesis, anterior bankart repair, posterior bankart repair and rotator cuff repair. Surgeon placed shaver inside shoulder and turned the device on. Immediately after the shaver was turned on it began to spit out metal shavings. The arthroscopic shaver was immediately removed from the field and the patient's shoulder was irrigated copiously. Another device was

		obtained and the procedure was completed with no further issues. There was no injury to the patient. The equipment was sequestered for risk management.
Smith & Nephew, Inc., Dyonics Full Radius Elite	7210909, C9405A, 50551426	The arthroscopic surgery blade is used to shave the ligament. This device is used in most arthroscopic procedures. Prior to shaving the physician noticed the distal tip was bent. The physician secured a second blade and completed the procedure without incident. There was no patient harm.
Smith & Nephew, Inc., Dyonics Synovator	7205334 , N/A, 50261	Patient was taken to surgery for right knee arthroscopy with meniscus repair. Upon using the smith and nephew Dyonics 4.5mm Synovator blade, metal like fragments were given off by the instrument. The surgeon immediately stopped using the instrument and removed it from the field. The device was in oscillating mode, was shaving the patient's meniscus and was not being torqued in any manner. The surgeon flushed out the fragments with copious amounts of saline to flush out the particulate. Another Synovator blade was used to finish the procedure. There was no injury to the patient, who was sent to the PACU for recovery after the procedure was finished.
Smith & Nephew, Inc., Dyonics Stonecutter	7205330 , N/A, 50546377	During room set up, it was noticed that the blade was sticking. The device was removed immediately and never made it to the pt.
Smith & Nephew, Inc., Dyonics Synovator	7205334, N/A, 50530083	Patient was taken to surgery for knee arthroscopy and meniscectomy. While using the smith and nephew curved Synovator blade the surgeon encountered a problem in that the shaver was "binding up" and not rotating freely (this instrument should spin freely allowing the surgeon to shave bone as needed in orthopedic surgical cases). Once this problem was encountered the surgeon stopped using the Synovator and utilized another device to complete the case. The procedure was finished and the patient was sent to the PACU for recovery. The device was retained for risk management. There was no injury to the patient.
Smith & Nephew, Inc., Dyonics Synovator	7205334, 375941000, 50530083	Patient taken to surgery for arthroscopy of the left knee with partial lateral meniscectomy. Upon using the smith and nephew Dyonics arthroscopic surgery blade, it appeared to start "flaking" at the

		sharp shaving point, leaving metal shavings in the patient's joint. Surgeon immediately discontinued use of the shaver and irrigated the pt's joint with copious amounts of saline to flush out the shavings until none were visible. Another shaver was used to complete the procedure. No further issues were noted. Patient tolerated the procedure well and was sent to the PACU for recovery.
Stryker Endoscopy, Formula Aggressive Plus	375-544-000, N/A, 10273CE2	During arthroscopy metal fragments were identified floating in the knee space. The physician stopped the procedure, irrigated and suctioned-out all the fragments from the knee space. A new shaver was obtained and the procedure was continued.
Smith & Nephew, Inc., Dyonics Incisor Plus Elite	7210976, , N/A, 50551293	Adolescent was taken to surgery to repair a right knee lateral bucket-handle meniscal tear. During arthroscopy, the smith and nephew Dyonics arthroscopic surgery incisor plus elite blade gave off what was believed to be small metal fragments in the pt's joint. The surgeon stopped using the blade and thoroughly irrigated the joint to flush out all the fragments. The MD was able to use a different blade to finish the procedure. There was no injury to the pt. The blade was sequestered and bagged for risk management pick-up. The patient tolerated the procedure well and was sent to the PACU for recovery
Ascent Healthcare Solutions, Formula Aggressive Plus	375-544-000, N/A, 1316606	The tip of the shaver blade broke off while the surgeon was doing an arthroscopy on the patient's right knee. The surgeon had to retrieve the broken piece from the patient's right knee.
Smith & Nephew, Inc., Dyonics Synovator	N/A, N/A,	Surgical technician reports, while testing equipment prior to a surgical procedure, it was noted the 4.5 mm curved arthroscopic shaver would not "spin." two more shavers of the same type and lot number were opened and also would not work properly. They would not spin effectively when attached to the surgical drill. A straight shaver (same manufacturer/different model number) was tested and worked appropriately. This replacement shaver was used for the remainder of the procedure. Once the procedure was complete the surgical technician bagged the shavers which were tested and did not work. He also removed 10 more shavers from the same lot number off of our

		shelves. Product has been retained in risk management and will be returned, upon request, to the manufacturer for testing purposes. There was no injury to the patient since products never reached the surgical field.
Smith & Nephew, Inc., Dyonics	7205315, N/A, 50541073	Elderly patient was taken to the or for left knee arthroscopy. During the procedure it was noted the smith & nephew Dyonics 4.5mm Turbotrimmer blade (shaver) appeared to be producing small metallic shavings. Or staff changed out the shaver blade and proceeded with the case with no further issues noted. Staff report it appeared shavings were washed out of knee capsule and the surgeon did not direct staff to do anything else in regards to this. Patient was sent to the PACU for recovery and was discharged home. The device was retained and sequestered for risk management pick up. Of note, we have had reports of this previously with other devices from other manufacturers and was told this may be "lubricant" flaking off. We have also seen this issue with reprocessed shavers from this same manufacturer. No apparent injury or impact to patient.
Ascent Healthcare Solutions, Formula	375-941-012, ES-9263A, 1112775	AS THE SURGEON WAS PERFORMING SHOULDER ARTHROSCOPY, THE 4MM SHAVER BLADE HE WAS USING EXPELLED PIECES OF METAL.
Conmed Corp., Sterling Full Radius Resector	C9248, 9263A, 193035	During a procedure, the MD tried to use a full radius resector and the device failed to spin. The device was removed from the site and the MD tried to clean out the sheath. It was noted that the inner part of the resector had broken in half, no part was missing. The part was replaced and surgery continued. No harm to the patient.
Ascent Healthcare Solutions, Dyonics Stonecutter	N/A, N/A, 1209432	Patient was in the or for left shoulder arthroscopy. During the procedure the orthopedic surgeon felt the reprocessed Dyonics stonecutter shaver was dull. Surgeon was able to complete procedure with the device but felt the device did not perform to the standards he was used to seeing. Note this was a different orthopedic surgeon than those described in the 2 previous dull shaver blade reports. There was no injury to the patient.
Ascent Healthcare	7205329, N/A,	Patients were scheduled for right ACL

Solutions, Dyonics Notchblaster	1045689	reconstruction surgery. During both procedures, while the orthopedic surgeon was using Dyonics reprocessed Notchblasters, he noted the burrs to be dull while in use. The devices did work, but the surgeon felt the devices were not as effective as compared to new or unused arthroscopic burrs. Of note, these were two separate procedures for two separate patients. Both devices are from the same lot number and both have been retained for evaluation purposes. There was no injury to the patients; however extra surgical time was necessary to ensure each Notchblaster completed the task they were used for.
Linvatec Corp., Sterling Tiger	C9242, 375-940-000, 187829	Shaver was in use when a piece of the device went "off field" and into the patient's knee.
Ascent Healthcare Solutions, Dyonics Incisor Plus Elite	N/A, N/A, 1221408	ADULT MALE TAKEN TO OR FOR ROTATOR CUFF REPAIR PROCEDURE. DURING THE SURGERY THE SURGEON WAS USING A REPROCESSED DYONICS (A SMITH & NEPHEW COMPANY) TURBO TRIMMER AND INCISOR PLUS ELITE SHAVER WHICH BOTH GAVE OFF WHAT APPEARED TO BE METAL SHAVINGS OR PARTICULATE WHEN USED. THE SURGEON NOTED SHAVINGS AND/OR PARTICULATE IN THE PATIENT'S JOINT. SURGEON HAD TO USE A HIGH-FLOW LAVAGE TO IRRIGATE THE METAL FRAGMENTS OUT OF THE SURGICAL SITE. SURGEON'S NOTE INDICATED THIS LAVAGE WAS SUCCESSFUL AND IT IS BELIEVED NO FRAGMENTS WERE RETAINED. BOTH SHAVERS WERE TAKEN OUT OF SERVICE AND SEQUESTERED FOR RISK MANAGEMENT. THERE WAS NO HARM OR INJURY TO THE PATIENT. SURGEON DID UTILIZE A THIRD SHAVER WHICH WORKED APPROPRIATELY WITHOUT GIVING OFF ANY SHAVINGS. PROCEDURE WAS FINISHED WITH NO FURTHER ISSUE.
Ascent Healthcare Solutions, Formula Round Bur 12 Flute	375-940-012, N/A, 1072147	Reprocessed shaver blade ascent formula round burr 12 flute used for case, metal shavings noted on video. Shaver blade changed, wound irrigated, no obvious metal shavings, reprocessed blades removed from or core supply.

Ascent Healthcare Solutions, Formula Aggressive Plus Cutter	N/A, Bonecutter, 1145308	Cutter broke off at tip. Broken tip was retrieved.
Smith & Nephew, Inc., N/A	N/A, N/A, 50515812	Metal findings emitted from arthroscopic shaver during knee scope.
Ascent Healthcare Solutions, Formula Aggressive Plus Cutter	375-564-000, Tomcat, 914742	The surgeon was using the device when he observed one of the blades had bent upward. The device was removed immediately and appeared to be intact.
Stryker Endoscopy, Formula Round Bur 6-Flute	375-940-000, 375-534-000, 10154CE2	A 4.0mm aggressive plus and 4.0mm burr (Stryker arthroscopic shavers) sterile packaged from the company were placed on the field in a sterile fashion. The scrub noted a white thick greasy substance on both the burr and incisor - the tips were removed from the field - packages were saved and devices bagged.
Ascent Healthcare Solutions, Formula Aggressive Plus Cutter 3.5mm	N/A, N/A, 969549	Stryker aggressive plus cutter 3.5 mm that was reprocessed by ascent. Upon insertion, the MD noticed silver particles falling on the meniscus prior to any shavings being performed. Item taken off field and given to or manager. Wound flushed several times.
Stryker Endoscopy, Formula Tomcat	375-545-000, N/A, N/A	During a shoulder arthroscopy, the surgeon reported seeing what appeared to be metal shavings from a stryker brand disposable arthroscopy blade. No patient injury was noted, since the area was thoroughly flushed and suctioned to remove all traces of the metal shavings. The stryker representative was notified and all blades from our inventory were replaced with blades from a different lot.
Stryker Instruments, Instruments Div, Formula Aggressive Plus	N/A, N/A, 753682	Cutter blade broke off out of shaver stem while in use. Metallic element was recovered by surgeon; however, x-ray was requested by surgeon to be done in PACU to rule out (r/o) any possibility of left behind fragments. No harm to the patient.
N/A, N/A	N/A, N/A, N/A	Cutter blade broke off out of shaver stem while in use. Metallic element was recovered by surgeon.
Smith & Nephew, Inc., Dyonics Bonecutter	7206010, 375-544-000, 996654	After just a few seconds of use under no particular lateral strain the reprocessed shaver blade started to spew out metal filings into the irrigated space during right knee arthroscopy. These appeared as glitter on the video screen. The area was rinsed out

		and no filings were left in the patient. A new, un-reprocessed blade was used after that with no difficulties encountered.
Ascent Healthcare Solutions, Formula Resector Cutter	375-562-000, N/A, 165724	The patient was having right shoulder arthroscopic debridement, subacromial decompression, distal clavicle resection, open rotator cuff repair, and open biceps tenodesis, right shoulder. The surgeon made a 4 cm incision across the anterolateral aspect of the shoulder. Dissection was carried through the subcutaneous tissue and the anterolateral border from the acromion was opened as was the deltoid split between the anterolateral heads. The rotator cuff tear was identified. The surgeon took a bur and debrided the bone to allow good bleeding. The surgeon then used pull stitches to mobilize the rotator cuff. Once the bur was used, it was noted that it left tiny pieces of metal in the patient's shoulder.
Ascent Healthcare Solutions, Formula Agressive 6 Flute	375-940-000, N/A, 140679	The male patient was having left shoulder arthoscopic rotator cuff repair, subacromial decompression, distal clavicle resection and debridement of a type 1 superior labral tear. The physician noted the patient did have a type 1 slap tear. His subscapularis tendon was intact. The type 1 slap lesion was debrided using a motorized shaver. After this was accomplished, the patient was noted to have a small, full-thickness rotator cuff tear that could be observed from the undersurface. This area was marked. The subacromial space was entered. Subacromial decompression was performed using a motorized bur. Once the bur was used, it was noted that it left very tiny flakes of metal inside the patient's shoulder.
Smith & Nephew Inc., Endoscopy Div., Dyonics	72200080, 7205330, N/A	Surgeon performing arthroscopy of patient's right ankle using 2 different Dyonics arthroscopic surgery blades. One noted to disintegrate upon use (shavings visible on video monitor) and another appeared to be winding tightly when end of shaver outside patient snapped off. Instruments were replaced and surgery completed without apparent injury to patient.
Ascent Healthcare Solutions, Gator	9263A, 375-941-012, 756924 - ASCENT LOT#	A 4.2mm arthroscopic shaver, remanufactured by ascent, began to leave what appeared to be metal shavings in the patients knee during an arthoscopy

		of the knee. This was noticed immediately by the surgeon and the shaver's use was discontinued. A new product was obtained that had not been remanufactured. The debris was suctioned out and irrigated. The procedure continued without incident.
Linvatec Corp., Gator	9263A, N/A, 756924 - ASCENT LOT #	Procedure: right shoulder arthroscopy with rotator cuff repair. Used an ascent reprocessed gator blade 4.2mm x 13 cm ref. *596a lot # 756924 2009-07. The doctor noted metal shavings being left behind in shoulder while using gator blade on the handpiece durnig the procedure.
Stryker Endoscopy, Formula	375747000, 7210976; 7205315, 09203CE2	Metal piece broke off end cutter. Metal piece was retrieved. Fluoroscopy confirmed there was no retained foreign body. No harm to patient.
Ascent Healthcare Solutions, Conmed Linvatek Blade	H9101,C9248 ,67631	During a shoulder arthroscopy with glenohumeral debridement acromioplasty distal clavicle resection, it was noted that there appeared to be minute metal shavings in the space/wound. Irrigated copiously until clear.
Ascent Healthcare Solutions, Formula	375-542-000, 7205315 ,676560	During the case the blade was "dull, not sharp."
Ascent Healthcare Solutions, Formula	375-941-000, 7205334 ,676230	During use, a lot of metal debris was seen floating; presumed to be from the bur. The debris was suctioned out.
Ascent Healthcare Solutions, Formula	375-542-000, 375-544-000, 676560	During the case it was noted that this burr was dull ("not sharp"). No other problems associated with the burr.
Stryker Endoscopy,.Formula 180	N/A, 7210976, 08226CE2	During the case observed on screen multiple metal flecks floating while presumably using the Stryker barrel bur. Surgeon suctioned them out.
Ascent Healthcare Solutions, Blade	7205305, 7210909, 210573	Device clogged and would not function.
Stryker Endoscopy, Formula Core And Formula 180	N/A, 7205334, N/A	Stryker issuing a cleaning reminder to ensure tissue does not remain on shaver (prior to sterilization).
Stryker Endoscopy, Agressive Plus	375544000, 7205334, 675348	Surgeon reported that blade was "grinding on itself", was ineffective.
Smith & Nephew, Inc., N/A	720611, 375-544-000, N/A	Recall of resection blades that may have breached sterile barrier. Warehouse discarded blades in stock.

Linvatec Corp., Ultracut	C9405A, 7205334, BBF22361	During shoulder arthroscopy a 4.2mm Ultracut disposable blade was used and physician found metal shavings inside the patient's shoulder, coming off of or out of the shaver blade. A second blade was opened and utilized, with no problems to finish procedure. Physician washed the shavings out of the patient's shoulder.
Stryker Endoscopy, Small Joint Aggressive Cutter	375628000, 7205330, 08224CE2	During wrist arthroscopy Stryker shaver blade broke off in patient's wrist times two, two different blades.

Additional Information:

US Food and Drug Administration, Medical Devices, List of Single-Use Devices Known To Be Reprocessed or Considered for Reprocessing, Retrieved February 18, 2011,from US Department of Health and Human Services Web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121090.htm